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Engagement practices that join scientific methods with community wisdom: Designing a patient-centered, randomized control trial with a Pacific Islander Community

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Abstract

This article illustrates how a collaborative research process can successfully engage an underserved minority community to address health disparities. Pacific Islanders, including the Marshallese, are one of the fastest growing US populations. They face significant health disparities, including extremely high rates of type 2 diabetes. This article describes the engagement process of designing patient-centered outcomes research with Marshallese

stakeholders, highlighting the specific influences of their input on a randomized control trial to address diabetes. Over 18 months, an interdisciplinary research team used community-based participatory principles to conduct patient-engaged outcomes research that involved 31 stakeholders in all aspects of research design, from defining the research question to making decisions about budgets and staffing. This required academic researcher flexibility, but yielded a design linking scientific methodology with community wisdom.

Keywords

community-based participatory research; patient-centered outcomes research; Pacific Islanders; Marshallese; diabetes; health disparities

BACKGROUND

Community-based participatory research (CBPR) is an approach to research that includes community stakeholders as partners rather than subjects in the research process (Israel et al., 2010; Minkler, Blackwell, Thompson, & Tamir, 2003; Minkler & Wallerstein, 2010; Viswanathan et al., 2004). CBPR has emerged as an effective approach to addressing health disparities among disenfranchised communities facing health inequalities (Freudenberg & Tsui, 2014; Israel et al., 2010, 2010b; Minkler, 2010; Minkler & Wallerstein, 2010). CBPR can be conceived on a continuum with limited input from stakeholders on one end and full engagement of stakeholders in all aspects of research on the other end (Minkler & Wallerstein, 2010). The National Institutes of Health (NIH), the Agency for Health Research and Quality (AHRQ), and the Environmental Protection Agency (EPA) have promoted CBPR to varying degrees over the past twenty years. In 2010, the Patient-Centered Outcomes Research Institute (PCORI) was established with funding created through the Affordable Care Act. PCORI funds patient-centered outcomes research (PCOR) that evaluates research “questions and outcomes meaningful and important to patients and caregivers” (Frank, Basch, & Selby, 2014, p. 1513). PCORI states that “incorporating the patient perspective into health care research is inherently valuable and that including the end user of research in the research process enhances usefulness and speeds the uptake of research into practice” (Frank et al., 2014, p. 1514). Much like CBPR, PCOR promotes involvement of patients and other stakeholders in the entire research process.

Pacific Islanders are one of the fastest growing populations in the United States, and are underrepresented in research. Arkansas has the largest Marshallese community in the continental United States. The Marshallese have significant health disparities, which include high rates of type 2 diabetes, obesity, and infectious diseases (Center for Disease Control and Prevention, 2009; LeDoux, 2009; Minegishi et al., 2007; Woodall, Scollard, & Rajan, 2011; Yamada, Dodd, Soe, Chen, & Bauman, 2004). To understand the context of the Marshallese community’s health disparities, it is important to understand the historical relationship between the United States and the Republic of the Marshall Islands. The Marshall Islands consists of 1,156 individual islands and atolls in Micronesia. Between 1946 and 1958, the US military tested nuclear weapons in the Marshall Islands (Barker, 2012; Cooke, 2010; Guyer, 2001). These tests were equivalent in payload to more than 7,200

Hiroshima-sized bombs. The largest test had a yield of 15 megatons, over 1,000 times the strength of the bomb dropped on Hiroshima, and exposed Marshall Islanders to significant levels of nuclear radiation (Barker, 2012; Cooke, 2010; Dobyns & Hyrmer, 1992; Guyer, 2001; Niedenthal, 1997). The Marshallese who lived on the bombed islands and atolls were relocated. However, Marshallese living on nearby atolls were not relocated, and they suffered immediate and long-term exposure to nuclear fallout (Conard, Dobyns, & Sutow, 1970; Dobyns & Hyrmer, 1992; Guyer, 2001; Yamada, 2004). According to the Atomic Energy Commission, the Marshall Islands are one of the most contaminated places in the world (Cooke, 2010). There have been numerous studies between 1965 and 2004 that have documented the ongoing health effects from the nuclear testing (Conard & Hicking, 1965; Dobyns & Hyrmer, 1992; Hamilton, van Belle, & LoGerfo, 1987; Howard, Vaswani, & Heotis, 1997; Kroon et al., 2004; Lessard, Miltenberger, Cohn, Musolino, & Conard, 1984; Pollock, 2002; Takahashi et al., 2003). In the midst of the nuclear testing, US scientists developed Project 4.1 to be implemented in the Marshall Islands in order to study the effects of nuclear radiation on humans (Barker, 2012). Exposed Marshall Islanders were interned in a camp on Kwajalein Atoll to be studied, and research was conducted without informed consent and without translation of study information into their native language (Barker, 2012).

In 1986, the United States and the Republic of the Marshall Islands signed the Compact of Free Association (COFA), which granted the US military exclusive use and control over a strategic portion of the Pacific and also allows the Marshallese to freely migrate to the United States without a visa (108th United States Congress). The Marshallese first arrived in Springdale, Arkansas, in 1986 after the COFA was signed. The relatively strong economy and low cost of living in northwest Arkansas continues to attract Marshallese migrants, with the population doubling between 2000 and 2010 (Jimeno, 2013). Approximately 10,000 Marshallese reside in northwest Arkansas. There are over 2,000 Marshallese students enrolled in the local school districts, and 93% of these students report speaking Marshallese at home (Springdale School District, 2014). Other sizable populations of Marshallese reside in Hawaii, California, Washington, Utah, and Oklahoma, and there is frequent travel between these states and Pacific Territories. The largest employer of the Marshallese in Arkansas is the poultry industry; 76% of employed Marshallese individuals work for *Tyson Foods*, *George's*, and *Butterball* (Jimeno, 2013).

While COFA migrants can freely enter the United States without a visa, they are not US citizens and are ineligible to vote. The COFA migrant status also limits their access to many health and public benefits. Prior to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), commonly referred to as welfare reform, COFA migrants were eligible for federally-funded health care programs including Medicaid and the Children's Health Insurance Program. However, PRWORA excluded COFA migrants from the category of "qualified immigrants" for purposes of eligibility for federal public benefits including Medicaid (Asian and Pacific Islander American Health Forum, 2014; McElfish, Hallgren, & Yamada, 2015; U.S. Government Printing Office, 1996; United States Court of Appeals for the Ninth Circuit, 2014). The limited access to health care further exacerbates the health inequalities of this underserved and vulnerable population.

Research with the Marshallese community is constrained by a lack of prevalence data specific to the Marshallese living in the United States and is complicated by their lack of access to health care (McElfish, Hallgren, et al., 2015). Furthermore, the Marshallese have been skeptical of participating in research because of the historical trauma originating from the nuclear testing in their islands and subsequent medical experiments (Barker, 2012). The University of Arkansas for Medical Sciences Northwest is committed to a CBPR approach that engages Marshallese stakeholders to overcome these challenges to research, and collaboratively addresses the health disparities identified and prioritized by the Marshallese community (McElfish, Kohler, et al., 2015).

This article describes the process of developing patient-centered outcomes research with the full engagement of Marshallese patients and community stakeholders. Specifically, the article provides information on the process used and the specific ways that community stakeholders input shaped the research design and PCORI proposal. PCORI requires “meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the research process—from topic selection through design and conduct of research to dissemination of results” (PCORI, 2015). PCORI holds “that such engagement can influence research to be more patient centered, useful, and trustworthy and ultimately lead to greater use and uptake of research results by the patient and broader healthcare community” (PCORI, 2015). PCORI provides an engagement rubric that outlines: 1) what they require for stakeholder engagement; 2) their requirements for judging the level of stakeholder engagement; and 3) their requirements for stakeholder engagement in planning a study, conducting a study, and disseminating the study results (Beal & Sheridan, 2014; PCORI, 2014). Components of the PCORI engagement rubric are utilized to evaluate our engagement process and organize the article.

METHODS

In 2011, the lead investigator became aware of the significant health disparities of the Marshallese community, and began meeting with Marshallese community members, Marshallese community organizations, and Marshallese churches with the goal of setting a community-driven research agenda using a CBPR approach. There are only two Marshallese community organizations in Arkansas: the Arkansas Coalition of Marshallese and Gaps in Services to the Marshallese Taskforce. The lead researcher partnered with these two community organizations, the Marshallese Consulate, and Marshallese churches to conduct a needs assessment. This needs assessment process took 18 months and used a mixed-methods design of qualitative interviews and a broad quantitative survey of the community. This mixed-methods needs assessment process is described in a separate article (McElfish, Kohler, et al., 2015). The top priority identified by the Marshallese community was type 2 diabetes (Center for Disease Control and Prevention, 2009; Hallgren, McElfish, & Rubon-Chutaro, 2015; McElfish, Kohler, et al., 2015). In order to address type 2 diabetes, the lead investigator brought together a diverse interprofessional research team and engaged 31 community stakeholders, including patients, family members, and health care providers (hereafter referred to as “stakeholders”) to begin planning an appropriate intervention with community support. The stakeholders included 16 patients with diabetes, 11 family members of patients with diabetes, and 4 community health care providers (see Table 1).

Representatives from the two Marshallese community based organizations, the Marshallese Consulate, and Marshallese churches were included as either patients or family members of patients and represented these groups as well as their organizations. Discussions were conducted both in English and in Marshallese (the native language) depending on the preference of stakeholders. Since the researchers did not speak Marshallese, a bilingual translator provided verbal interpretation and took notes in English. The freedom to use their native language increased the stakeholders comfort and shifted the power of gaining knowledge and sharing information to the stakeholder.

Following stakeholder input from preliminary planning, an interprofessional CBPR team was formed and included: two Marshallese community co-investigators, two academic investigators with expertise in CBPR, two individuals holding the Pharm.D degree and a nurse diabetes educator to provide diabetes education, a PhD-prepared biostatistician with expertise in comparative effectiveness research, and two endocrinologists with expertise in the treatment of type 2 diabetes.

Over an 18-month period, between June 2012 and December 2013, the CBPR team engaged in multiple discussions with stakeholders regarding all aspects of the research design and PCORI proposal. As outlined in Table 2, and described below, decisions regarding the project took multiple meetings with stakeholders and often more than one element of the research design was discussed at each meeting. The information for this article is derived from the process notes from our research meetings. The PCORI application, as well as this article, was written with full involvement of the two Marshallese community co-investigators.

PROCESS AND RESULTS

Formulating research questions

The research question was formulated by starting with the community's articulation of a health issue. Our prior needs assessment showed there was clear agreement within the broader Marshallese community and among stakeholders that the priority health issue was type 2 diabetes. Seventy-five percent (75%) of the Marshallese chose type 2 diabetes as a top concern (Center for Disease Control and Prevention, 2009), and prevalence data documented that between 20% and 50% of Marshallese adults have type 2 diabetes (McElfish, 2012–2013; Minegishi et al., 2007; Yamada et al., 2004). The lead researcher then worked with Marshallese community co-investigators through an iterative process to articulate an overarching research question that was meaningful to stakeholders: *As a Marshallese family with type 2 diabetes, what can we do to manage our family's diabetes and improve health outcomes?* This research question was brought back to the larger group of stakeholders for confirmation.

Choosing/creating the intervention to be studied

Stakeholders (patients, family members, and community health care providers) discussed a wide range of intervention options to address diabetes including the diabetes prevention program (DPP) and the diabetes self-management education (DMSE) program. Based upon

the large number of Marshallese who currently have diabetes, the stakeholders chose DSME as the first intervention to test within their community. The lead researcher shared information from previous attempts by other researchers to implement DSME in the Marshallese community and facilitated conference calls with the investigators of those studies to learn from the successes and failures of their research (Reddy, Shehata, Smith, & Maskarinec, 2005; Reddy, Trinidad, Seremai, & Nasa, 2009). In addition, the lead researcher facilitated discussions with local practitioners to understand their previous attempts of implementing DSME within the Marshallese community and the lessons learned from those attempts. Then the CBPR team and community stakeholders collaboratively discussed the current state of knowledge and what should be collaboratively examined in order to design an effective diabetes intervention.

The stakeholders hypothesized that one of the primary reasons for poor outcomes in previous studies was a lack of culturally appropriate implementation of DSME. Stakeholders pointed out that the delivery method and the concept of self-management as an individual experience were problematic components. DSME is designed with an individualistic, Western societal approach. The Marshallese have a highly collectivist culture, and the idea of “self” management is counter to their cultural values. Marshallese stakeholders described, “We eat together from one pot. For one person to refuse the food from that one pot is not just inconvenient, it is shameful. It shames the person and the person’s family. It is not an acceptable option. We will not do it” (McElfish, 2013). The Marshallese stakeholders also explained that any changes to eating habits and behavior must be focused on the family unit in order to be effective, and stakeholders reinforced that incorporating collectivist and family-centered concepts into the DSME curriculum and delivery method was imperative. Stakeholders recommended that DSME be implemented within an extended family model so additional family members could benefit and the patient with diabetes would be supported by their family members (Hallgren et al., 2015; McElfish et al., 2016). Stakeholders continue to work side by side with researchers to culturally adapt DSME for implementation in a family model (McElfish, Bridges, et al., 2015).

Involvement in research design

Collaborative research design is often one of the most difficult components of CBPR and PCOR because stakeholders often lack research education and experience with scientific methods and basic tenets of research. However, research design is also an area in which the successful engagement of stakeholders can reap the most benefits, particularly in choosing a research design that will be most feasibly implemented in the community (Minkler & Wallerstein, 2010). To facilitate discussions on research design, conversations on individual components of research were discussed in practical, lay terms so that they were accessible to stakeholders of varying educational levels. The results of these discussions are presented below.

Comparison/control group—There was significant discussion with stakeholders regarding the need for a comparison or control group. Stakeholders wanted to enroll all participants into the new family model DSME group. However, researchers articulated the need for a comparative design to meet PCORI methodological standards (Basch et al.,

2012). Researchers and stakeholders discussed several different types of control groups including wait-list, no intervention, and standard care. The choices were narrowed to a wait-list control group or a standard care DSME control group. The stakeholders chose the standard care DSME control because they felt it would be most acceptable to the community. To further incorporate the stakeholders' guidance, the CBPR team's biostatistician created an uneven randomization process that assigned more participants to the family model DSME group. This collaborative design allowed researchers to balance both scientific rigor and stakeholder input.

Participant assignment—Another area with considerable discussion was the use of random assignment of study participants to a factorial arrangement of intervention groups. Researchers felt it was imperative to the study design. Stakeholders felt that it was important to allow participants to choose the intervention they would receive. The PCORI Methodology Standards were shared with stakeholders, and the CBPR team collaboratively discussed the strengths and weakness of random assignment. While the discussion of participant assignment was an area of significant disagreement, debate, dialogue, and education, in the end, stakeholders did agree on a random assignment design.

Outcomes of importance and study instruments—A wide range of potential intervention outcome measures were discussed with stakeholders utilizing an inductive process with open-ended questions including: a) What should we measure?; b) What outcomes are important to you?; and c) How would you measure success? After much discussion, stakeholders were asked to prioritize outcome measures. The most important outcomes identified were: 1) understanding what I need to do to be healthy; 2) being able to take care of myself; and 3) managing my blood sugar.

Healthcare providers and researchers recommended that changes in hemoglobin A1c (HbA1c) be the primary outcome measure for statistical analysis (Norris, Lau, Smith, Schmid, & Engelgau, 2002). Stakeholders agreed HbA1c should be the primary outcome measure for power analysis and determination of the sample size. To capture and evaluate other outcomes, stakeholders agreed that validated instruments were preferred. Instruments validated in minority populations, with a preference for those validated for use with Pacific Islanders and/or Marshallese, were collected. Several validated instruments from the Michigan Diabetes Research and Training Center (University of Michigan, 2015) were reviewed by stakeholders and CBPR team members and evaluated for their appropriateness to collect patient preferred outcome measures. After selecting instruments, the CBPR team and stakeholders adapted the instruments for language and culture. The research team compiled a list of important confounding variables and ensured that the instruments captured those for analysis. This list of variables and corresponding questions were shared and confirmed with stakeholders.

Participant characteristics—Stakeholders also had a strong voice in determining participant characteristics. Specifically, researchers' definition of "family" was biased by an understanding of a traditional, nuclear family. However, stakeholders explained that the Marshallese have a much broader definition of family and use the same word for mother and aunt and for sister and cousin. Therefore, the definition of "family" for the research study

was defined broadly enough to include these extended family members. For the purposes of the study, “family” is defined by the primary participant with diabetes and can include any household member that the participant considers to be part of their family.

Recruitment—Stakeholders also provided specific input on research operations. After discussing the best recruitment methods, stakeholders recommended utilizing a multi-pronged approach of clinic recruitment, church-based recruitment, and social media recruitment, to allow for the most representative sample of the Marshallese community to be recruited. The multiple methods proposed by stakeholders allow us to reach those who may or may not have a primary care provider, attend church, or use social media. Without this input from stakeholders, the study may have relied solely on clinic-based recruitment.

Data collection intervals and retention—Data collection intervals created more discussion than researchers anticipated. Initially, stakeholders felt that pre/post-test data collection was sufficient and did not want to extend data collection events to six and twelve months. Discussions required that academic researchers share the current state of DSME literature and explain why additional data collection events were necessary. Stakeholders continued to voice their concern with retaining participants through twelve months, which led to more intensive dialogue and the formulation of a retention plan. While stakeholders still feel retaining and tracking Marshallese participants will be challenging, they have become committed to the additional data collection events and are leading the development of a strong retention plan. The retention plan designed by stakeholders includes utilizing both social media and a case management approach.

Staffing and resource sharing—There were extensive discussions concerning project staff and resource sharing. The primary input from stakeholders was that field staff should: 1) be members of the Marshallese community; 2) be bilingual (in English and Marshallese); and 3) have a basic understanding of the healthcare system. Stakeholders discussed whether or not the project staff should be employees of the university or hired through a subcontract with community-based organizations. After much discussion, stakeholders decided that because of the regulations governing human-subjects’ protection and data security, the project staff should be university employees. In addition, the stakeholders wanted the project staff to have access to the benefits available to university employees, which includes a significant tuition discount for employees and their families. Other areas, including outreach and coordination of the stakeholder engagement board, were subcontracted to community-based organizations. Stakeholders also made decisions on the amount of remuneration that should be provided to community co-investigators, stakeholders, and the advisory board for their time and effort.

Language and cultural protocols—Based upon input from stakeholders, the research study that was designed is conducted in either Marshallese (native language) or English, depending on the preference of the participants. Furthermore, the stakeholders outlined important cultural protocols including how to properly engage with elders and different genders, as well as nuances in verbal and non-verbal communication.

Consensus decision making

A consensus model for decision making, which sought broad input from community stakeholders, was used throughout the entire research design process. Stakeholders were encouraged to share their perspectives with a focus on what decision would advance the success of the research project while also balancing community and cultural aspects with research design, regulatory, and financial constraints. The consensus process required significant time to explain complex research methodology as well as a willingness to listen and trust the knowledge and wisdom of community stakeholders (see Table 2). Researchers and community stakeholders had easy and quick agreement on some items (staffing and resource sharing; recruitment; participant characteristics; outcomes of importance), but other topics (comparison/control groups; random assignment) included significant discussion, education, and compromise between the stakeholders and researchers. Final decisions were facilitated by the community co-investigators and the lead investigator who focused on collaborating to ensure decisions that all stakeholders could support, even if it was not their first choice.

Community Review Board

While the entire research design and writing process was collaborative, the CBPR team decided to hold a formal Community Review Board (CRB). During the CRB, stakeholders reviewed the major tenets of the proposal and provided feedback. For example, stakeholders reviewed and confirmed processes for recruitment, participant assignment, and data collection. There were no significant changes after the CRB process because the design decisions and the writing process were done collaboratively prior to the CRB. However, the formal CRB process was helpful because it allowed the community to confirm their prior input was incorporated into the proposal. It also allowed broad ownership of the research.

Community Advisory Board

The 31 stakeholders who provided input on the application did so as an informal collaborative. Only the two community co-investigators who are part of the CBPR team have a formal, long-term commitment to the project. However, the stakeholders developed an ongoing formal Community Advisory Board (CAB) that will ensure the research will maintain patient centeredness throughout the implementation of the study. The CAB of patients and patients' families is a smaller group of nine stakeholders. The CAB continues to meet monthly and provides input throughout the implementation process to monitor the conduct of the research. A broader group of stakeholders is updated quarterly at community forums.

Community co-investigators

Two community stakeholders were selected by the broader group to serve as community co-investigators as part of the CBPR team. The community co-investigators are leaders within the community, but had little health care or research background. The community co-investigators serve roles similar to other university investigators and have decision-making authority in the research process. Their primary purpose is to ensure the Marshallese community's input and priorities are maintained throughout the research process.

Implementation of a pilot project and PCORI Award

While some CBPR collaborations have been successful in providing semi-formal research education to their research partners, our process has been characterized more as “learning by doing.” After the submission of the PCORI grant proposal in January 2014, the CBPR team maintained involvement with the stakeholders and began a small feasibility pilot study with six families (McElfish, Bridges, et al., 2015) funded through departmental funding and a small foundation grant. The small pilot allowed the CBPR team to continue to work together after the PCORI application was submitted, and allowed stakeholders to immediately see the process and results of the research project they designed. The pilot project also provided stakeholders the opportunity to learn more about the research process and allowed researchers to benefit from the experience and the results of stakeholder input. In October 2014, PCORI funding was awarded as a three year contract. The community advisory board and the CBPR team culturally adapted the DSME curriculum and refined the process based on the lessons learned in the pilot study. Participant enrollment began in May 2015.

Analysis and dissemination

While analysis for the larger family model study, funded by PCORI, will not begin until 2017, stakeholders have been involved in the analysis of pilot data. Although patient stakeholders have only wanted limited involvement in the quantitative analysis, they have been more intensively involved in the qualitative data analysis (Hallgren et al., 2015; McElfish et al., 2016). Community co-investigators have shown significant interest and ownership in how the data is interpreted and disseminated. Community co-investigators have given six presentations related to our research collaboration, the pilot study, and current progress on the PCORI-funded research, and academic researchers have made five presentations. The early presentations by community co-investigators have allowed for broader dissemination to community, policy, healthcare providers, and academic audiences, while researcher presentations have been limited to academic and healthcare provider audiences. In addition, all articles related to our CBPR partnership and research have included the opportunity for community co-authorship.

DISCUSSION

Much of the prior literature has outlined the principles and processes for CBPR, but have not provided specific details of how those processes resulted in specific changes to conceptualization and conduct of research. Furthermore, many CBPR scholars eschew randomized control trials as inappropriate for CBPR, and there is little literature published on how to engage patients in the process of designing randomized control trials. The PCORI engagement rubric pushes the field forward by providing a practical tool to measure the process and outcome of engagement, and perhaps most importantly, apply engagement practices to comparative effectiveness research that is often conducted with randomized control trials. This article provides an example of how patient-engaged methods can be used to design and conduct a randomized control trial with a population who has been underrepresented in research and suffered significant historical trauma. In doing so, this article adds to the current engagement literature and encourages researchers and funding

agencies to examine their practices to encourage inclusive engagement of stakeholders in all kinds and at all levels of research.

When stakeholders were asked what worked well and what did not work well concerning the engagement and consensus decision making process, they stated: “You listened to us. We told you what we want to do and you helped us do it. We are doing it together. It is hard to make the meetings and talk about research, but we are not just being studied by some outsiders, we are doing the research, and we are doing the research on something that we want, not just what the researchers want. I don’t really understand research sometimes, but I understand my community and that is important too” (McElfish, 2013).

Broad stakeholder input set the research agenda for our CBPR team, and then continued to provide input on all aspects of the research design. Stakeholder input has made a significant difference in the research design of our PCORI application. The inclusion of stakeholders in research opens the protocol to multiple and divergent points-of-view, which requires greater flexibility of the researcher, a willingness to explain complex research methodology and the methodological requirements of funders to stakeholders, and a willingness to change study designs to ensure community support. Even after the stakeholders and research team make a decision on the protocol or operations, additional discussion was often required and sometimes those discussions led to change. This fluid process continues to require open and extensive dialogue to balance community wisdom with scientific methods.

While much progress has been made in our CBPR partnership with the Marshallese community, we acknowledge that PCOR and CBPR, with full involvement of multiple stakeholders, requires significant time, effort, flexibility, and financial resources, and there are many potential impediments to the process. Most of the barriers we experienced are within the university system rather than the community. Our current research enterprise is designed to operate in a principal investigator model and rewards research that is conducted independently rather than collaboratively. In order to address health disparities and translate research into better health, more interprofessional, patient-centered, community-engaged research is needed. This entails a much more facilitative process and academic researchers who are willing to engage in research that they do not design on their own. Our current academic research incentive and promotion structure is not designed to support this type of research. In order for CBPR and PCOR to be implemented broadly, university research must create structures that promote and reward more collaborative, interprofessional, and facilitative models of research that focus on meeting patient and community needs.

CONCLUSION

Research with underserved, minority populations who have experienced significant historical trauma is strengthened through true stakeholder engagement. Utilizing a fully-engaged CBPR process, community stakeholders and the interprofessional community-academic research team designed a randomized control trial through multiple discussions about the research question, intervention, participant assignment, comparison group, data collection intervals, instrument selection, and recruitment. We had easy and quick agreement on some items while other topics included significant debate, education, and compromise

between the stakeholders and community and academic researchers. As a result, we developed a hybrid research design that joins the scientific process with the wisdom of the community. Balancing the input, opinions, and desires of stakeholders with the requirement of a rigorous research design proved to be both challenging and invigorating.

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Table 1

Stakeholders

Patients	16
Family members of patients	11
Healthcare providers	4
Total	31

Note: Representatives from two Marshallese community based organizations, the Marshallese Consulate, and Marshallese churches are included as either patients or family members of patients and represented these groups as well as their organizations.

Table 2**Stakeholder Involvement**

Area discussed	# of meetings	Who was involved in the discussion and decisions	Specific design elements selected / changed because of stakeholder involvement
Establish the priority need	39 meetings over two years	Broad community input from patients, family members, health care providers, and community leaders with the lead researchers	Focus on type 2 diabetes as the top concern
Research question	4 meetings over 2 months	Broad community input from patients, family members, health care providers, community leaders, and interprofessional research team	The research question was based on family rather than the individual outcomes
Intervention	5 meetings over 2 months	Broad community input from patients, family members, health care providers, community leaders, and interprofessional research team	The intervention is based on a family model of DSME rather than an individual model of DSME
Research design	7 meetings over 5 months	Broad community input from patients, family members, health care providers, community leaders, and interprofessional research team	Two active arms comparing a traditional model and the new family model of DSME
Participant assignment	3 meetings over 2 months	Broad community input from patients, family members, health care providers, community leaders, and interprofessional research team	Unequal assignment allows for methodological rigor and meets the desires of stakeholders to include more participants in the new family model
Participant characteristics	7 meetings over 5 months	Broad community input from patients, family members, health care providers, community leaders, and interprofessional research team	Family participants will be more broadly defined for a culturally appropriate definition of family
Outcomes of importance	9 meetings over 5 months	Broad community input from patients, family members, health care providers, community leaders, and interprofessional research team	Both standard biometric and broader lifestyle outcomes were chosen
Recruitment	4 meetings over 2 months	Broad community input from patients, family members, health care providers, and community leaders with the lead researchers	Three recruitment methods were combined to allow for broader representation of the Marshallese community
Retention	4 meetings over 2 months	Broad community input from patients, family members, health care providers, and community leaders with the lead researchers	Retention will utilize social media and a case management approach
Staffing and resource sharing	4 meetings over 2 months	Broad community input from patients, family members, health care providers, and community leaders with the lead researchers	Research staff will be bilingual and have cultural skills; Subcontracts will be provided to community-based organizations; Stakeholders determined the amount that community co-investigators, the CAB, and participants would be provided
Dissemination	1 meeting over 1 month with ongoing discussion	Broad community input from patients, family members, health care providers, and community leaders with the lead researchers	Broader dissemination beyond traditional academic stakeholders